

Package leaflet: Information for the user

Dalmevin 50 mg tablets

Vildagliptin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or diabetes nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Dalmevin is and what it is used for

The active substance of Dalmevin, vildagliptin, belongs to a group of medicines called “oral antidiabetics”.

Dalmevin is used to treat adult patients with type 2 diabetes. It is used when diabetes cannot be controlled by diet and exercise alone. It helps to control the level of sugar in the blood. Your doctor will prescribe Dalmevin either alone or together with certain other antidiabetic medicines which you will already be taking, if these have not proved sufficiently effective to control diabetes.

Type 2 diabetes develops if the body does not make enough insulin or if the insulin that the body makes does not work as well as it should. It can also develop if the body produces too much glucagon.

Insulin is a substance which helps to lower the level of sugar in the blood, especially after meals. Glucagon is a substance which triggers the production of sugar by the liver, causing the blood sugar level to rise. The pancreas makes both of these substances.

How Dalmevin works

Dalmevin works by making the pancreas produce more insulin and less glucagon. This helps to control the blood sugar level. This medicine has been shown to reduce blood sugar, which may help to prevent complications from your diabetes. Even though you are now starting a medicine for your diabetes, it is important that you continue to follow the diet and/or exercise which has been recommended for you.

2. What you need to know before you take Dalmevin

Do not take Dalmevin:

- If you are allergic to vildagliptin or any of the other ingredients of this medicine (listed in section 6). If you think you may be allergic to vildagliptin or any of the other ingredients of Dalmevin, do not take this medicine and talk to your doctor.

Warnings and precautions

Talk to your doctor, pharmacist or diabetes nurse before taking Dalmevin:

- If you have type 1 diabetes (i.e. your body does not produce insulin) or if you have a condition called diabetic ketoacidosis.
- If you are taking an anti-diabetic medicine known as a sulphonylurea (your doctor may want to reduce your dose of the sulphonylurea when you take it together with Dalmevin in order to avoid low blood glucose [hypoglycaemia]).
- If you have moderate or severe kidney disease (you will need to take a lower dose of Dalmevin).
- If you are on dialysis.
- If you have liver disease.
- If you suffer from heart failure.
- If you have or have had a disease of the pancreas.

If you have previously taken vildagliptin but had to stop taking it because of liver disease, you should not take this medicine.

Diabetic skin lesions are a common complication of diabetes. You are advised to follow the recommendations for skin and foot care that you are given by your doctor or nurse. You are also advised to pay particular attention to new onset of blisters or ulcers while taking Dalmevin. Should these occur, you should promptly consult your doctor.

A test to determine your liver function will be performed before the start of Dalmevin treatment, at three-month intervals for the first year and periodically thereafter. This is so that signs of increased liver enzymes can be detected as early as possible.

Children and adolescents

The use of Dalmevin in children and adolescents up to 18 years of age is not recommended.

Other medicines and Dalmevin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Your doctor may wish to alter your dose of Dalmevin if you are taking other medicines such as:

- thiazides or other diuretics (also called water tablets),
- corticosteroids (generally used to treat inflammation),
- thyroid medicines,
- certain medicines affecting the nervous system.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not use Dalmevin during pregnancy. It is not known if Dalmevin passes into breast milk. You should not use Dalmevin if you are breast-feeding or plan to breast-feed.

Driving and using machines

If you feel dizzy while taking Dalmevin, do not drive or use machines.

Dalmevin contains lactose

Dalmevin contains lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Dalmevin contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

3. How to take Dalmevin

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How much to take and when

The amount of Dalmevin people have to take varies depending on their condition. Your doctor will tell you exactly how many tablets of Dalmevin to take. The maximum daily dose is 100 mg.

The usual dose of Dalmevin is either:

- 50 mg daily taken as one dose in the morning if you are taking Dalmevin with another medicine called a sulphonylurea.
- 100 mg daily taken as 50 mg in the morning and 50 mg in the evening if you are taking Dalmevin alone, with another medicine called metformin or a glitazone, with a combination of metformin and a sulphonylurea, or with insulin.
- 50 mg daily in the morning if you have moderate or severe kidney disease or if you are on dialysis.

How to take Dalmevin

- Swallow the tablets whole with some water.

How long to take Dalmevin

- Take Dalmevin every day for as long as your doctor tells you. You may have to take this treatment over a long period of time.
- Your doctor will regularly monitor your condition to check that the treatment is having the desired effect.

If you take more Dalmevin than you should

If you take too many Dalmevin tablets, or if someone else has taken your medicine, **talk to your doctor straight away**. Medical attention may be needed. If you need to see a doctor or go to the hospital, take the pack with you.

If you forget to take Dalmevin

If you forget to take a dose of this medicine, take it as soon as you remember. Then take your next dose at the usual time. If it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Dalmevin

Do not stop taking Dalmevin unless your doctor tells you to.

If you have questions about how long to take this medicine, talk to your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some symptoms need immediate medical attention:

You should stop taking Dalmevin and see your doctor immediately if you experience the following side effects:

- Angioedema (rare: may affect up to 1 in 1,000 people): Symptoms include swollen face, tongue or throat, difficulty swallowing, difficulties breathing, sudden onset rash or hives, which may indicate a reaction called “angioedema”.
- Liver disease (hepatitis) (frequency not known): Symptoms include yellow skin and eyes, nausea, loss of appetite or dark-coloured urine, which may indicate liver disease (hepatitis).
- Inflammation of the pancreas (pancreatitis) (rare: may affect up to 1 in 1 000 people): Symptoms include severe and persistent pain in the abdomen (stomach area), which might reach through to your back, as well as nausea and vomiting.

Other side effects

Some patients have had the following side effects while taking vildagliptin:

- Very common (may affect more than 1 in 10 people): sore throat, runny nose, fever.
- Common (may affect up to 1 in 10 people): itchy rash, trembling, headache, dizziness, muscle pain, joint pain, constipation, swollen hands, ankles or feet (oedema), excessive sweating, vomiting, pain in and around the stomach (abdominal pain), diarrhoea, heartburn, nausea (feeling sick), blurred vision.
- Uncommon (may affect up to 1 in 100 people): weight increase, chills, weakness, sexual dysfunction, low blood glucose, flatulence.
- Rare (may affect up to 1 in 1 000 people): inflammation of the pancreas.

Since vildagliptin has been marketed, the following side effects have also been reported:

- Frequency not known (cannot be estimated from the available data): localised peeling of skin or blisters, blood vessel inflammation (vasculitis) which may result in skin rash or pointed, flat, red, round spots under the skin's surface or bruising.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or diabetes nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Dalmevin

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Dalmevin contains

- The active substance is vildagliptin. Each tablet contains 50 mg vildagliptin.
- The other ingredients are: microcrystalline cellulose, lactose anhydrous, sodium starch glycolate (Type A) and magnesium stearate.

What Dalmevin looks like and contents of the pack

Dalmevin 50 mg tablets are white to light yellowish, round flat bevel edged uncoated tablet plain on both sides with diameter 8 mm.

Dalmevin 50 mg tablets are available in blisters in boxes containing 7, 14, 28, 30, 56, 60, 90, 112, 180, 336 tablets in blisters.

Not all pack sizes may be marketed in your country.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Medochemie Ltd, 1-10 Constantinoupoleos Street, 3011 Limassol, Cyprus

Manufacturer

Medochemie Ltd. - Central Factory, 1-10 Constantinoupoleos Street, 3011 Limassol, Cyprus

This medicinal product is authorized in the Member States of the EEA under the following name:

Sweden	Dalmevin
Bulgaria	Далмевин 50 mg таблетки
Croatia	DALMEVIN 50mg tablete
Cyprus	DALMEVIN 50mg δισκία
Czech Republic	DALMEVIN
Estonia	DALMEVIN
Greece	DALMEVIN 50mg δισκία
Latvia	DALMEVIN 50mg tabletes
Lithuania	DALMEVIN 50mg tabletės
Malta	DALMEVIN 50mg tablets
Romania	DALMEVIN 50mg comprimate
Slovak Republic	DALMEVIN 50mg tablety

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